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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/125,329      | 09/08/98    | PORTMANN             | R 4-30028/A/PC      |

001095  
THOMAS HOXIE  
NOVARTIS CORPORATION  
PATENT AND TRADEMARK DEPT  
564 MORRIS AVENUE  
SUMMIT NJ 07901-1027

HM12/1013

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| EXAMINER |
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MORRIS, P

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| ART UNIT | PAPER NUMBER |
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1625

DATE MAILED: 10/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/125,329

Applicant(s)

Portmann et al

Examiner

J. Morris

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 9/6/00
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-9, 13, 14, 16-21 and 26-31 is/are pending in the application.
- Of the above claim(s) 27 and 29 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-9, 13, 14, 16-21, 26, 28, 30 and 31 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 are under consideration in this application.

Claims 27 and 29 are held withdrawn from consideration as being drawn to a nonelected invention 37 CFR 1.142(b).

### ***Election/Restriction***

Newly submitted claims 27 and 29 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants now have added for first time claims drawn to a patentably distinct invention, ie., methods of use.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27 and 29 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 are rejected under 35 U.S.C. 102(a), (b), (e) and/or (f) as being anticipated by Meier I, II for the reasons set forth in Paper no. 5.

Again, Meier I, II disclose the crystal form of the instant compound obtained by recrystallization from ethanol. Note example 35 of Meier I or example 4 of Meier II. Hence, the instant compound is deemed to be anticipated therefrom.

Contra to applicants' arguments in the instant response, the factual situation here is well within the "Petering doctrine": In re Petering et al., 49 CCPA 993, 301 F.2d 676, 133 USPQ 275 (1962). There the court affirmed a 102(b) rejection on the ground that the prior art, while it did not expressly name applicants' claimed compounds, did describe such a limited class of only twenty compounds "that one skilled in this art would at once envisage each member of this limited class, even though this skilled person might not at once define in his mind the formal boundaries of the class as we have done here" (133 USPQ at 280). Here we do not have anywhere near twenty possible compounds within the limited class described by the references.

Also, where a reference describes a sufficiently limited genus of a number of compounds closely related to another in structure, the reference may be said to provide a description of those compounds just as if they were identified in the reference by name. In re Schaumann, 572 F.2d 312, 197 USPQ 5 (CCPA 1978).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Meier I, II in view of Munzel I, II for the reasons set forth in Paper no. 5.

Again, Meier I, II teach the crystal forms of the instant known compound. However, Meier I, II does not disclose the lines with interplanar spacings of the X-ray powder pattern of said form or other characterizing parameters thereof, whereas the instant claims disclose specific X-ray diffraction pattern for the claimed compounds. Munzel I, II teach that compounds exist as polymorphs and retain pharmaceutical activity. Hence the claimed crystalline form as well as its relative selectivity of properties *vis-a-vis* the known compound are suggested by the references. It would appear obvious to one skilled in the art in view of the references that the instant compound would exist in different polymorphic forms.

Applicants argue that the Meier references do not suggest or teach the crystalline forms discovered by applicants or a method of making the crystalline forms. However, it is well known in the art that compounds exist in different crystalline forms. One of ordinary skill in the art would have been motivated to make these crystalline forms with the expectation that they would

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have better solubility, stability and/or purity. The process by which the different crystalline forms are produced are likewise known in the art. No unexpected or unobvious properties are noted.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Again, the expression "essentially pure form" in claims 9 and 21 is meaningless and fails to clearly define what is intended by applicants.

Regarding claims 7, 16-20, 30 and 31, the phrase "but has defects in the crystal lattice" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed thereby rendering the scope of the claim(s) unascertainable. It is assumed that the claimed compounds are no longer identical to "modification A". Further, claims 7, 16-20, 30 and 31 fail to specify what the defects are. What are the defects?

Contra to applicants' arguments in the instant response, one cannot tell from a simple reading of the claim what is being claimed. One must first conceive of the pure forms and all possible defect. Then one must, by preparing the compound himself, determine if the unknown

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form or the forms with all the unknown defects works or not. Where is the specific claiming and distinctly pointing out? How can applicants regard as their invention inexact concepts? The breadth of which they could not have possibly checked out with representative exemplification. The terms are not finite.

Applicants are claiming a compound of the formula. Pure chemistry, a compound. Not a resin of general property ranges, but a pure compound. That compound used for any purpose is taken from the public in a 20-year monopoly to applicants. Then, the public is entitled to know what compound they cannot use. Yet, the claim is not specific to that compound. The public cannot tell what they may not use. How is a claim of the instant breadth defensible in an infringement action?

As applied to pure compounds, In re Cavallito and Gray, 134 USPQ 370, and In re Sus and Schaefer, 134 USPQ 301, are considered to set the proper applicable standard of required definiteness and support.

Applicants assert that the modifications A and A' are identical. Hence, claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 are substantial duplicates.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 14 and 20 of U.S. Patent No. 4,789,680 in view of Munzel I, II for the reasons set forth in Paper no. 5.

As set forth supra, '489 disclose crystal forms of the instant known compound. Munzel I, II teach that the mere existence of further polymorphs of compounds is not in itself regarded as unexpected. Hence, patentable distinction is not seen.

A terminal disclaimer has not been received too date.

Claims 1-9, 13, 14, 16-21, 26, 28, 30 and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims copending Application No. 09/599,699 in view of Munzel I, II.

Ser. no. 09/125,330 is now abandoned and 09/599,699 is the continuing application.

Again, Ser. no. 09/599,699 teaches the crystal form B of the claimed compound. Munzel I, II teach that polymorphs are expected to exist. Hence, the instant crystal form is deemed to be an obvious optional variant of the crystal form B.

This is a provisional obviousness-type double patenting rejection.



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*Conclusion*

Applicant's arguments filed September 6, 2000 have been fully considered but they are not persuasive.

No claim is allowed.

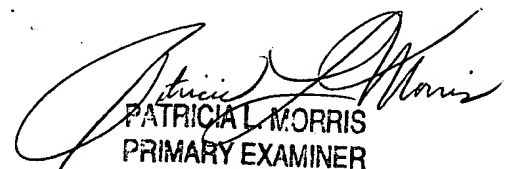
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.

plm

October 12, 2000

  
PATRICIA L. MORRIS  
PRIMARY EXAMINER  
GROUP 120